



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-N-0375, FDA-2013-N-0520, FDA-2008-D-0031, FDA-2012-N-0386, FDA-2013-N-0377, FDA-2011-D-0147, FDA-2013-N-1588, FDA-2013-N-0093, and FDA-2016-N-1593]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at

<https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a

person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Table 1.--List of Information Collections Approved By OMB

Title of Collection	OMB Control Number	Date Approval Expires
Agreement for Shipment of Devices for Sterilization	0910-0131	9/30/2022
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910-0339	9/30/2022
Clinical Laboratory Improvement Amendments Waiver Applications	0910-0598	9/30/2022
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products	0910-0650	9/30/2022
Tobacco Health Document Submission	0910-0654	9/30/2022
Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence Requirements for Tobacco Products	0910-0673	9/30/2022
Exemptions From Substantial Equivalence Requirements for Tobacco Products	0910-0684	9/30/2022
Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts and 351(k) Biologics License Applications in Biosimilars User Fee Act	0910-0746	9/30/2022
Medical Device Accessories	0910-0823	9/30/2022

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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